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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	05284.00130	9920

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

10

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,791

Applicant(s)

HUNG, DAVID

Examiner

Ulrike Winkler

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 10, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 5, 9. 6) ☐ Other: _____

Art Unit: 1648

DETAILED ACTION

Applicant's election without traverse of Group I with the species election of papilloma virus in Paper No. 8 is acknowledged.

In order to facilitate the prosecution of this application, Applicant is requested to consider inserting a claim drawn solely to the above elected species and canceling all non-elected embodiments from the claims.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 4, 5 and 9, are attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required. It is noted that figure 2 provide no informative information that would assist in the understanding of the invention. Applicant might want to consider omitting the figure entirely.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Please see page 11, line 21, applicant is advised to check the entire application and remove all hyperlinks.

Art Unit: 1648

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al. (U.S. Pat. No. 6,221,622, IDS) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), Makita et al. (Breast Cancer Research, 1991, IDS), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirolgy 1997) and Androphy (Ciba Found. Symposium, 1986).

The instant invention is drawn to a method comprising the steps of obtaining fluid and washing fluid from a single breast duct and analyzing the sample for the presence of a viral agent. The viral agent is identified with a viral marker (whole virus, protein or nucleic acid). The invention further comprises treating a patient at risk by administering an antiviral agent.

Art Unit: 1648

The antiviral agent can be administered through catheter to the breast duct or the agent can be administered systemically.

A recitation of the intended use "identifying a patient at risk of developing breast cancer or pre-cancer" of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The term "identifying a patient at risk of developing breast cancer or pre-cancer" is being viewed as an intended use which confers no further substance to the claim and is given little patentable weight (see *In re Pearson*, 494 F.2nd 1399, 1403, 181 USPQ 641, 664 (CCPA 1974)).

Love (U.S. Pat. No. 6,221,622, IDS) teaches a method of obtaining cellular material from a single breast duct using a double lumen catheter that allows for the simultaneous insertion and withdrawal of fluid from a single duct. The duct washing is used for diagnostics an evaluation can be made on a duct-by-duct basis (see summary of invention). The epithelial cells, other cells and non cellular material obtained by this method can be examined morphologically, histochemically and immunohistochemically for cancer or pre-cancer conditions present in the lining of the duct, non-cellular material released into duct can also be examined (see column 3, lines 39-46, and claims). The reference teaches the ability to irrigate (introduce fluid) and wash (remove fluid) from a single breast duct and using the material for the analyses of precursor cancer markers. The reference teaches that ducts may be washed multiple times. In addition the

Art Unit: 1648

reference suggest that treatment can be applied to an effected duct (column 1, line 53-56). The reference does not specifically teach detecting a viral agent, the reference uses terms such as cancer or pre-cancer conditions. This broad category encompasses viral agents, which are known to be involved in the cancer pathology.

Sukumar et al. (U.S. Pat. No. 5,763,415) teaches the use of cannulation of the breast duct to introduce an epithelial cell destroying agent/vector into a breast duct at risk of developing solid tumors. The reference does not teach using a virus specific agent. The composition used by the reference destroys epithelial cells, which are the cells that are infected by papillomavirus. The reference acknowledges the advantage of treating a single duct, which will result in the preservation of the remainder of the breast tissue. The reference establishes that at the time the invention was made that it was known in the art to introduce a treatment agent into the breast duct.

Makita et al. (Breast Cancer Research, 1991, IDS) teaches using duct endoscopy to obtain a biopsy sample from a single breast duct, followed by analyzing the sample to see if the contains a viral agent, such as papilloma (table 1). The reference establishes that at the time the invention was made it was known in the art that papillomavirus is present in the epithelial cells of the breast duct.

King et al. (JNCI, 1983, IDS) teaches that fluid obtained from nipple aspirate can be used to assess the presence of a viral agent, papilloma and papilomatosis (see table 5). The reference obtains fluid from multiple ducts and not a single duct. The reference establishes that at the time the invention was made it was known in the art that papillomavirus can be detected in

Art Unit: 1648

fluid samples obtained from breast ducts. The reference does not teach infusion of the breast duct with antiviral agents after discovering the presence of a viral agent.

Noguchi et al. teach using PCR analysis to determine the presence of papillomavirus in the breast duct. In this reference the samples were obtained from surgical samples and not from fluid extractions of the breast. The reference does teach the correlation between multiple intraductal papillomavirus lesions and pre-cancerous lesions (see discussion). The reference does establish that it was known in the art at the time the invention was made to use the sensitive PCR technique to detect papillomavirus in samples.

Androphy (Ciba Found. Symposium, 1986) teaches the use of interferon for the treatment of papillomavirus. Treatment may be giving intralesionally or systemically (see abstract). The reference established that it was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

Gross G (Intervirolgy) teaches that interferon and other immunotherapies can be used to treat papillomavirus infection. The interferon may be administered systemically or topically or intralesionally (see page 370 column 1). The reference established that it was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

The prior art establishes that it was known to introduce/extract washing fluids using a dual lumen catheter. The prior art established that it was known to introduce therapeutic agents into the breast duct directly. It was also known the prior art that papillomavirus lesion were found in the breast duct. Based on what was known in the prior art at the time the invention was made it would have been obvious to one of ordinary skill in the art to (1) utilize a duct washing system for the diagnosis of the presence of a viral agent in the breast duct and (2) utilize a duct

Art Unit: 1648

washing system for the diagnosis of the presence of a viral agent followed by the introduction of an antiviral agent to the patient. One having ordinary skill in the art would have been motivated to use the cellular and non cellular material extracted by the dual lumen catheter as taught by Love in conjunction with assays for the presence of papillomavirus in the breast duct. Makita et al., King et al. and Noguchi et al. each establish that the presence of papillomavirus in the epithelial layers of the breast duct was known in the art. Optimizing the diagnostic condition with repeated sample analysis would be an obvious step to the ordinary artisan. If the timing of the monitoring step provides an unexpected result, applicant needs to point out what the unexpected results are. Applying a therapeutic antiviral agent to the breast duct would be obvious. Love teaches that a therapeutic agent can be applied using the double lumen catheter. Sukumar et al. teach the introduction of a composition into the breast duct, which destroys the epithelial tissue a primary site for papillomavirus infection. Androphy and Gross teach the use of interferon for the treatment of papillomavirus, the interferon can be administered directly to the papillomavirus lesion or it can be administered systemically. Optimizing the treatment condition would be an obvious step to the ordinary artisan.

The prior art teaches that papilloma lesion are present in the breast duct, the prior art teaches the collection of fluid and cells from a breast duct for the purpose of determining the presence of papillomavirus by cytochemical and histochemical analysis. The prior art teaches treatment of papillomavirus by administering the interferon to a patient either topically or systemically. Therefore, taken what was known in the prior art as a whole it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to

Art Unit: 1648

identify the presence of papillomavirus in a single breast duct and apply treatment to the single breast duct.

Conclusion


No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER 4/18/07